

Notice of Allowability

Application No.

10/082,001

Examiner

Chih-Min Kam

Applicant(s)

DEMUTH ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/15/04.
2. ☒ The allowed claim(s) is/are 1-10 and 14-22.
3. ☒ The drawings filed on 22 February 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 11/26/03
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 20041025.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

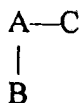
Authorization for this examiner's amendment was given in a telephone interview with John Serio on October 26, 2004.

Examiner's Amendments to the Claims:

Please cancel claims 11-13 and 23-25.

Claims 1, 4 and 14 have been amended as follows:

1. (Currently amended) A dipeptidyl peptidase IV (DP-IV) inhibitor compound of the general formula



wherein

A is an amino acid having at least one functional group in the side chain,

B is a chemical compound covalently bound to at least one functional group of the side chain of A, chosen from the group consisting of:

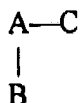
(a) oligopeptides having a chain length of up to 20 amino acids, except for homopolymers of glycine consisting of up to 6 glycine monomers, and

(b) polyethylene glycols having molar masses of up to 20 000 g/mol; and

C is a group amide-bonded to A, chosen from the group consisting of thiazolidine, pyrrolidine, cyanopyrrolidine, hydroxyproline, dehydroproline and piperidine.

4. (Currently amended) The compound according to claim 1, wherein the amino acid of A is chosen from the group consisting of threonine, tyrosine, serine, arginine, lysine, aspartic acid, glutamic acid and cysteine.

14. (Currently amended) A pharmaceutical composition comprising at least one dipeptidyl peptidase IV (DP-IV) inhibitor compound of the general formula



wherein

A is an amino acid having at least one functional group in the side chain,

B is a chemical compound covalently bound to at least one functional group in the side chain of A, chosen from the group consisting of:

- (a) oligopeptides having a chain length of up to 20 amino acids, except for homopolymers of glycine consisting of up to 6 glycine monomers, and
- (b) polyethylene glycols having molar masses of up to 20,000 g/mol,
- [(c) optionally substituted organic amines, amides, alcohols, acids or aromatic compounds having from 8 to 50 carbon atoms,]

C is a group, amide-bonded to A, chosen from the group consisting of thiazolidine, pyrrolidine, cyanopyrrolidine, hydroxyproline, dehydropyrolidine and piperidine, [pyrrolidide provided that, when B is selected from (c), then C can not be pyrrolidine or cyanopyrrolidine;]

and at least one pharmaceutically acceptable carrier [material].

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

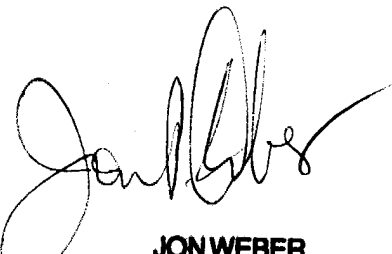
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

CMK
October 26, 2004



JON WEBER
SUPERVISORY PATENT EXAMINER